# What is the optimal proportion of dietary fat, CHO and protein to avoid regain in weight-reduced persons?

#### Conclusion

A moderate body of evidence provides no data to suggest that any one macronutrient is more effective than any other for avoiding weight re-gain in weight reduced persons.

#### Grade: Moderate

Overall strength of the available supporting evidence: Strong; Moderate; Limited; Expert Opinion Only; Grade not assignable For additional information regarding how to interpret grades, eliek here

#### **Evidence Summary Overview**

This conclusion is based on 12 articles published since 2004: Two review articles, nine randomized controlled trials (RCTs) and one prospective cohort study (Benassi-Evans, 2009; Dale, 2009; Due, 2008; Frisch, 2009; Hession, 2009; Lim, 2009; McAuley, 2005; Noakes, 2006; Nordmann, 2006; Phelan, 2007; Sacks, 2009; Westerterp-Plantenga, 2004). Studies were conducted in the Australia, Denmark, Germany, Israel, New Zealand, the Netherlands and the US. Studies ranged in length from one month to 24 months. Studies also ranged in sample size from 33 to 891 subjects, and had dropout rates from 12% to 34%. Diets tested ranged from 10% to 61% energy from fat, 15% to 36% energy fromprotein (PRO) and 4% to 70% energy from carbohydrate (CHO).

Ten studies found no difference in weight maintenance between diets differing in macronutrient proportion (Benassi-Evans, 2009; Dale, 2009; Due, 2008; Frisch, 2009; Lim, 2009; McAuley, 2005; Noakes, 2006; Nordmann, 2006; Phelan, 2007; Sacks, 2009). One study found that lowerCHO diets diet resulted in better weight maintenance than low-fat, low-calorie diets (Hession, 2009). One study found that a higher-protein diet resulted in better weight maintenance than a lower-protein diet (Westerterp-Plantenga, 2004).

## Evidence Summary Paragraphs (12)

#### Systematic Reviews and Meta-Analyses (2)

Hession et al, 2009 (positive quality) performed a systematic review and meta-analysis to assess the weight-loss effects of low-CHO diets compared with low-fat/low-calorie diets. Randomized controlled trialsconducted in adults with a BMI of  $28 \text{kg/m}^2$  or more that lasted for more than six months were included in the review. In addition, low-CHO diets were defined as "less than 60 g per day of CHO" and low-fat/low-calorie diets were defined as "less than 30 % energy from fat or -600 kcal deficit diet." At six months, weight change was -4.02 kg in favor of the low-CHO diets compared to the low-fat/low-calorie diets (P<0.0001) and by 12 months this difference was still significant at -1.05 kg (P<0.05).

Nordmann et al, 2006 (positive quality) performed a meta-analysis to compare the effects of low-CHO diets without energy restriction to energy-restricted low-fat diets on weight loss, blood pressure (BP) and lipid values in trials with dietary interventions with duration of at least six months. The final sample included five international RCTs. After six months, individuals assigned to low-CHO diets had lost more weight than individuals randomized to low-fat diets (weighted mean difference, -3.3kg; 95% CI: 5.3, -1.4kg). This difference was no longer obvious after 12 months (weighted mean difference, -1.0kg; 95% CI: -3.5, 1.5kg).

## Primary articles (10):

## Randomized Controlled Trials (9)

Benassi-Evans et al, 2009 (positive quality) conducted an RCT in Australia to compare the effects of high-CHO, low-red-meat and high-protein, high-red-meat weight loss diets on genome stability in peripheral blood lymphocytes inoverweight men. Subjects were assigned to one of two isocaloric, energy-restricted diets: high-CHO (17% PRO, 58% CHO, 25% fat, N=17) or high-PRO, high-red-meat (35% PRO, 40% CHO, 25% fat, N=16) diets for 12 weeks, followed by a 52-week weight maintenance period. Subjects met with the dietitian every two weeks for the first 12 weeks of the study, and then monthly until one year. Dietary intake for six days a month was assessed using checklists. The final sample included 33 men [mean age approximately 54 years; meabody mass index (BMI) 32kg/m²], with 17 subjects in the high-CHO group and 16 subjects in the high-protein group. Both diets produced an average weight loss of 9.3±0.7kg after 12 weeks, with no further change after 52 weeks.

Dale et al, 2009 (positive quality) conducted an RCT in New Zealand to compare the effectiveness of two support programs and two diets with differing macronutrient composition for long-term weight maintenance. Women who had lost 5% or more of their body weight were assigned to an intensive support program implemented by nutrition and activity specialists or to a nurse-led program involving "weigh-ins" and encouragement combined with either a high-CHO diet (55% CHO, 15% to 20% PRO, 25% to 30% fat) or high-monounsaturated fat diet (MUFA) (40% CHO, 25% PRO, 35% fat, 21% MUFA) diets. The final sample included 174 women (mean age 45 years; mean BMI 32kg/m²) who were followed for two years, with 42 subjects in the high-CHO intensive group, 45 in the high-MUFA intensive group, 47 in the high-CHO nurse group and 40 in the high-MUFA nurse group. Attrition rate was 13%. Average weight loss (approximately 2kg) did not differ between those in the support programs (0.1kg; 95% CI: -1.8, 1.9; P=0.95) or diets (0.7kg; 95% CI: -1.1, 2.4; P=0.46).

Due et al, 2008 (positive quality) conducted an RCT conducted in Denmark to compared the effects of three diets on maintenance of an initial weight loss of 8% or more and risk factors for cardiovascular disease(CVD) and diabetes. Subjects were randomly assigned for six months to either a high-MUFA diet (45% CHO, 15% PRO, 40% fat, more than 20% MUFA, N=54), a low-fat diet (60% CHO, 15% PRO, 25% fat, N=51) or a control diet (50% CHO, 15% PRO, 35% fat, N=26). All foods were provided for free from a purpose-built supermarket and subjects received two counseling sessions with a dietitian. The final sample included 106 subjects (mean age 28.2±4.8 years; mearBMI 31.5±2.6kg/m²), with 39 subjects in the MUFA group, 43 in the low-fat group and 24 in the control group. Attrition rate was 13%. All groups regained weight (MUFA: 2.5±0.7kg; low-fat: 2.2±0.7kg; control:  $3.8\pm0.8kg$ ), but the groups did not differ. Body fat regain was lower in the LF (0.6±0.6%) and MUFA (1.6±0.6%) groups than in the control group (2.6±0.5%) (P<0.05).

Frisch et al, 2009 (positive quality) conducted a RCT in Germany to investigate whether the macronutrient composition of an energy-restricted diet influences the efficacy of a telemedically guided weight loss program. Subjects were assigned to either a low-CHO diet (less than 40% CHO, more than 35% fat, 25% PRO) or a low-fat diet (less than 30% fat, more than 55% CHO, 15% PRO). The intervention was delivered for six months, when subjects received nutrition education and dietary counseling by phone. Anthropometric, body composition and biochemical parameters were measured at baseline, six and 12 months. The final sample included 165 subjects (mean age  $47\pm10.5$  years; mearBMI =  $33\text{kg/m}^2$ ). Attrition rate was 17%. In both groups, energy intake decreased by 400kcal per day within the first six months and increased slightly during the second six months. After six months, weight loss was not significantly different between groups, with the low-CHO group losing  $7.2\pm5.4\text{kg}$  and the low-fat group losing  $6.2\pm4.8\text{kg}$ . Between six and 12 months, weight regain between the groups was borderline significant, with the low-CHO group regaining less weight  $(1.6\text{kg}; 5.8\pm6.1\text{kg} \, \text{lost})$  than the low-fat group  $(1.9\text{kg}; 4.3\pm5.1\text{kg} \, \text{lost})$ .

Lim et al, 2009 (neutral quality) conducted a RCT in Australia to compare the changes in weight and other cardiovascular risk factors associated with three isocaloric energy-restricted diets to no-intervention control after one year. Subjects were randomly allocated to either very-low-CHO (VLC; 60% fat, 4% CHO, 36% PRO; N=30), very-low-fat (VLF; 10% fat, 70% CHO, 20% PRO; N=30), high-unsaturated fat (HUF; 30% fat, 20% PRO, 50% CHO; N=30) with intensive support for three months followed by minimal support for 12 months, while the control group received no intervention. The final included 104 subjects (age 47±10 years;BMI of 32±6kg/m²), with 30 subjects in the VLC group, 30 subjects in the VLF group, 30 subjects in the Public proups and 23 subjects in the control group. Attrition rate at 15 months was 34%. Weight change at three months did not differ between diet groups and was -8.0±2.9kg for VLC, -2.0±0.1kg for VLC, and -3.7±0.1kg for HUF, and was significantly different from controls (+0.8±5.0kg; P<0.050. When all groups were combined, weight loss at 15 months was significantly correlated to a higherprotein intake (R=-0.38, P=0.0009), lower fat intake (R=0.31, P=0.037) and higher fiber intake (R=-0.30, P=0.038).

McAuley et al, 2005 (positive quality) conducted a RCT in New Zealand to compare the effects on weight loss of consuming either a high-fat Atkins diet, a high-protein Zone diet or high-CHO, high-fiber diet in obese, insulin-resistant women. The weeks one to eight of the study were intended to be a weight loss phase, weeks eight to 16 were a weight maintenance phase with similar supervision as the weight loss phase and for weeks 16 to 24 subjects were asked to continue following the intervention, but had no contact with the research team. None of the diets were formally energy-restricted and ad libitum consumption was advised for all subjects. The high-fat diet groups consumed 11% CHO, 29% PRO and 57% fat from one to eight weeks, and 26% CHO, 24% PRO and 46% fat from weeks eight to 24. The high-PRO group consumed 34% CHO, 28% PRO and 35% fat from weeks one to 24. The high-CHO group consumed 49% CHO, 21% PRO and 24% fat from weeks one to 24. The final sample included 84 women (mean age 45 years, meanBMI higher than 27kg/m²), 31 on the high-FRO diet and 32 on the high-CHO diet. Attrition rate was 12%. There were no differences in reported energy in all groups during the six-month trial. Between baseline and eight weeks, the high-fat group (96.0±10.8kg to 89.4±10.3kg), the high-PRO group .Between eight weeks and 24 weeks, the high-fat group (89.4±10.3kg to 88.9±10.6kg), the high-PRO group (87.8±13.7kg) and the high-CHO group (89.4±10.3kg to 88.9±10.6kg), the high-PRO group (87.8±13.7kg) all maintained their initial weight loss.

Noakes et al, 2006 (positive quality) conducted a RCT in Australia to compare the effects of a very-low-CHO, very-low-fat and a high-unsaturated fat diet on body composition and cardiovascular risk. Subjects were randomly assigned to one of three isocaloric diets for eight weeks of weight loss, followed by four weeks of energy balance: Very-low-fat (70% CHO, 10% fat, 20% PRO); high-unsaturated fat (70% CHO, 10% fat, 20% PRO); very-low-CHO (4% CHO, 61% fat, 20% PRO). Detailed dietary instruction and meal plans were provided to subjects every two weeks by a registered dietitian (RD), and daily dietary checklists were used to assess compliance with the study protocol. The final sample included 67 subjects (55 women and 12 men; mean age  $48\pm8$  years; mean BMI  $33\pm3$ kg/m<sup>2</sup>), with 24 on the very-low-CHO diet, 22 on the very-low-fat diet and 21 on the high-unsaturated-fat diet. Attrition rate was 19%. Each diet groups lost weight over the eight-week energy restriction period and maintained this weight during the subsequent four-week period. There were no significant (NS) differences in weight loss by diet composition; the very-low-CHO group lost  $8.0\pm0.6$ kg, the very-low-fat group lost  $6.7\pm0.7$ kg and the high-unsaturated-fat group lost  $6.4\pm0.6$ kg.

Sacks et al, 2009 (positive quality) conducted a RCT in the US to examine the effects on body weight of energy-reduced diets with differing macronutrient composition. Subjects were randomly assigned to one of four energy-reduced (-750 kcal per day) diet groups: Low-fat, average PRO (20% fat, 15% PRO, 65% CHO); low-fat, high PRO (20% fat, 25% PRO, 55% P

CHO); high-fat, average PRO (40% fat, 15% PRO, 45% CHO); or high-fat, high-PRO (40% fat, 25% PRO, 35% CHO). Subjects were offered group and individual counseling session for two years, and daily web-based food records were used to assess compliance with the study protocol. Weight measurements were taken at baseline, six months and two years. The final sample included 645 subjects (397 women, 248 men; mean age 52 years; mearBMI 33kg/m²). Attrition rate at two years was 20%. After six months, participants had lost an average of 6kg (approximately 7% of initial weight), but began to regain weight after 12 months, with no differences between the groups. At two years, weight loss remained similar in those assigned to the 15% protein and 25% protein diets (-3.0 and -3.6kg, respectively); in those assigned to the 20% and 40% fat diets (-3.3kg for both groups); and in those assigned to the 65% and 35% CHO diets (-2.9 and -3.4kg, respectively) (P>0.20 for all comparisons).

Westerterp-Plantenga et al, 2004 (positive quality) conducted an RCT in the Netherlands to investigate whether addition of protein may improve weight maintenance by preventing or limiting weight regain after weight loss of 5% to 10% in moderatelyobese subjects. Subjects were randomly assigned to a very low-energy diet (2.1mJ per day) for four weeks, with one group receiving a 48.2g per day protein supplement to add to their regular diet. The regular diet group consumed 15% of energy from protein and the additional protein group consumed 18% of energy from protein. The final sample included 148 subjects (mean age = 45 years; meanBMI 29kg/m²). After three months, percentage of weight regain (17% vs. 37%) was significantly lower in the higher-protein group compared to control (P<0.05).Body mass index was also significantly lower in the higher-protein group compared to control (27 vs. 28kg/m²; P<0.05).

### Prospective Cohort Studies (1)

Phelan et al, 2007 (neutral quality) conducted a prospective cohort study in the US to evaluated long-term weight loss and eating and exercise behaviors of successful weight losers who lost weight using a lowCHO diet. Data on three-year changes in weight, diet and physical activity were analyzed from 891 participants in the National Weight Control Registry from 1998 to 2001 who reported 30-lb or more weight loss and one-year or more weight loss maintenance. In this sample, 96 participants (10.8%) self-reported losing weight using a low-CHO diet (mean age 49.0±11.7 years; 54.2% male). There were NS differences in weight regain between these individuals and other Registry members in the intent-to-treat analysis (7.0±7.1kg vs. 5.7±8.7kg). Low-CHO diet participants were also more likely to have a shorter duration of successful weight maintenance (34.4±35.1 vs. 73.1±99 months; P=0.0001) compared with other Registry participants.

□ View table in new window

Author, Year, Study Design, Class, Rating	Population	Intervention (Initial / Intense Phase)	Intervention (F/U / Maintenance Phase)	Macronutrient Composition of Diet	Weight Outcomes (End of Initial / Intense Phase)	Weight Outcomes (End of F/U / Maintenance Phase)	Safety Outcomes
Benassi-Evans et al 2009 Study Design: Randomized Clinical Trial Class: A Rating:	N=33 men.  • N=17 in high-CHO group • N=16 in high-PRO group.  Age: 54 years.  BMI: 32kg/m².  Attrition: Not applicable.	Subjects were assigned to one of two isocaloric, energy restricted diets: High-CHO, low-red-meat or high-PRO, high-red-meat diets for 12 weeks. Subjects met with the RD every two weeks for the first 12 weeks of the study. Dietary intake for six days a month was assessed using checklists.	The initial 12-week intervention was followed by a 52-week weight maintenance period, during which time subjects met with the RD monthly.	CHO, PRO, Fat:  • High-CHO: 58%, 25%, 17%. • High-PRO: 40%, 25%, 35%.	Both diets produced an average weight loss of 9.3±0.7kg after 12 weeks.	No further weight Δ occurred in the 52-week weight maintenance period.	NS differences between the diets with regards to any of the measures of genome stability and cell death in lymphocytes, including micronucleus frequency, nuclear buds, nucleoplasmic bridges, necrosis, apoptosis and nuclear division index.
Dale KS et al 2009 Study Design: Randomized Controlled Trial Class: A Rating:	N=174 women.  • N=42 in high-CHO intensive group • N=45 in high-MUFA, intensive group • N=47 in high-CHO, nurse group • N=40 in high-MUFA, nurse group.  Age: 45 years.  BMI: 32kg/m².  Attrition rate: 13%.	Not applicable.	Women who had lost more than 5% weight were assigned to a support program implemented by nutrition and activity specialists or to a nurse-led program involving "weigh-ins" and encouragement combined with either a high-CHO diet or high-MUFA diet diets.  Women were followed for two years.	CHO, PRO, Fat:  • Intensive and high-CHO: 55%, 25% to 30%, 15% to 20%.  • Intensive and high-fat: 55%, 25% to 30%, 15% to 20%.  • Nurse and high-CHO: 40%, 35%, 25%.  • Nurse and high-fat: 40%, 35%, 25%.	Not applicable.	Average weight loss (~2kg) did not differ between those in the support programs (0.1kg; 95% CI: -1.8, 1.9; P=0.95) or diets (0.7 kg; 95% CI: -1.1, 2.4; P=0.46).	TC and LDL-C levels were significantly higher among those on the high-MUFA diet (0.17mmol per L, P=0.040 and 0.16mmol per L, P=0.039, respectively), than those on the high-CHO diet.
Due A et al 2008 Study Design: Randomized Controlled Trial Class: A Rating:	N=106 subjects.  • N=39 subjects in MUFA group • N=43 in low-fat group • N=24 in control group.  Mean age: 28 years.  Mean BMI: 32kg/m².  Attrition rate: 13%.	Not applicable.	Subjects who had lost more than 8% body weight were randomly assigned for six months to either a high-MUFA diet, a low-fat diet or a control diet.  All foods were provided for free from a	CHO, PRO, Fat:  • High-MUFA: 45%, 40%, 15% • Low-fat: 60%, 25%, 15% • Control: 50%, 35%, 15%.	Not applicable.	All groups regained weight (MUFA: 2.5±0.7kg; low-fat: 2.2±0.7kg; control: 3.8±0.8kg), but the groups did not differ. Body fat regain was lower in the	In the MUFA group, fasting insulin ↓ by 2.6±3.5pmol per L, the HOMA insulin resistance by 0.17±0.13, and LDL:HDL ratio by 0.33±0.13; in the LF group.  These variables ↑ by 4.3±3.0pmol per L (P<0.08) and 0.17±0.10 (P<0.05) and ↓ by 0.02±0.09

			purpose-built supermarket and subjects received two counseling sessions with an RD.			LF (0.6±0.6%) and MUFA (1.6±0.6%) groups than in the control group (2.6±0.5%) (P<0.05).	$\begin{array}{l} (P=0.005),\\ \text{respectively; and in}\\ \text{the control group,} \uparrow\\ \text{by } 14.0\pm4.3\text{pmol per}\\ \text{L } (P<0.001),\\ 0.57\pm0.17 \ (P<0.001)\\ \text{and } 0.05\pm0.14\\ (P=0.036), \text{ respectively.} \end{array}$
Frisch S et al 2009 Study Design: Randomized Controlled Trial Class: A Rating:	N=165. Age: 47 years. BMI: 33kg/m <sup>2</sup> . Attrition rate: 17%.	Subjects were assigned to a calorie-restricted diet (~-400kcal per day) that was either low-CHO or low-fat. The intervention was delivered for six months, when subjects received nutrition education and dietary counseling by phone. Anthropometric, body composition and biochemical parameters were measured at baseline and six months.	The weekly telephone counseling was discontinued during months six to 12.  Anthropometric, body composition and biochemical parameters were measured at 12 months.	CHO, PRO, Fat:  • Low-CHO: <40%, >35%, 25%. • Low-fat: <55%, <30%, 15%.	After six months, weight loss was NS between groups.  The low-CHO group lost 7.2±5.4kg and the low-fat group lost 6.2±4.8kg.	Between six and 12 months, weight regain between the groups was borderline significant (P<0.05), with the low-CHO group regaining less weight (1.6kg; 5.8±6.1kg lost) than the low-fat group (1.9kg; 4.3±5.1kg lost).	TG (-0.03±0.55mmol per L vs0.18±0.40mmol per L; P<0.001) and HDL-C levels (-0.09±0.19mmol per L vs0.02±0.20mmol per L; P<0.001) were significantly lower at six months and waist circumference (-4.7±8.9cm vs6.9±6.1cm; P<0.05) and SBP (-1±15mmHg; P<0.01) were significantly lower at 12 months in the low-CHO group compared to the low-fat group.
Hession M et al 2009 Study Design: Systematic Review Class: M Rating:	N=50 RCTs conducted in adults with BMI 28kg/m <sup>2</sup> or more lasting for more than six months.	Not applicable.	Not applicable.	CHO, PRO, Fat:  • Low-CHO: <60g per day CHO. • Low-fat, low-calorie: <30% fat.	At six months, weight $\Delta$ was -4.02kg in favor of the low-CHO diets compared to the low-fat/low-calorie diets (P<0.0001).	At 12 months, weight loss was still significantly less in the low-CHO diets compared to the low-fat diets at -1.05kg (P<0.05).	Compared to low-fat/low-calorie diets, there were significant improvements in HDL-C (0.04mmol per L at six months and 0.06mmol per L at 12 months, P<0.05), triacylglycerols (0.017mmol per L at six months and -0.19mmol per L at 12 months, P<0.05) and SBP (-1.35mm Hg at six months and -2.19mm Hg at 12 months, P<0.05) for subjects following low-CHO diets.  The high-CHO diets resulted in significant † in TC (0.19mmol per L, P<0.0001) at six months, and in LDL-C (0.14mmol per L and 0.37mmol per L) at six and 12 months, respectively (P<0.00001) compared to the low-fat/low-calorie diets.
Lim et al 2009 Study Design: Randomized Controlled Trial Class: A Rating:	N=104 subjects.  • N=30 in VLC group • N=30 in VLF group • N=30 in HUF group • N=23 in control group.  Age: 47 years.  BMI: 32kg/m².  Attrition rate at 15 months: 34%.	Subjects were randomly allocated to either very-low-CHO (VLC), very-low-fat (VLF) or high-unsaturated fat (HUF) with intensive support for three months, while the control group received no intervention.	The intensive three-month initial phase was followed by minimal support for 12 months.	CHO, PRO, Fat:  • VLC: 4%, 60%, 35%.  • VLF: 70%, 10%, 20%.  • HUF: 50%, 30%, 20%.	Weight ∆ at three months did not differ between diet groups and was -8.0±2.8kg for VLC, -6.7±3.5kg for VLF and -6.3±2.9kg for HUF.	Weight $\Delta$ at 15 months did not differ between diet groups and was -3.0±0.2kg for VLC, -2.0±0.1kg for VLF and -3.7±0.1kg for HUF, and was significantly different from controls (+0.8±5.0kg; P<0.050).  For all groups combined, weight loss at 15 months was	At 15 months, there were NS differences in weight $\Delta$ or cardiovascular risk factors between groups.

						significantly correlated to a higher PRO intake (R=-0.38, P=0.0009), lower fat intake (R=0.31, P=0.037) and higher fiber intake (R=-0.30, P=0.038).	
McAuley KA et al 2005 Study Design: Randomized Controlled Trial Class: A Rating:	N=84 obese, insulin-resistant women.  • N=31 on high-fat diet • N=30 on high-PRO diet • N=32 on high-CHO diet. Age: 45 years. BMI: >27kg/m². Attrition rate: 12%.	Weeks one to eight of the study were a supervised weight loss phase.  Subjects were randomized to one of three diet interventions, either:  • High-fat diet (Atkins) • High-PRO diet (Zone) • High-CHO, high-fiber diet.  None of the diets were formally energy-restricted and ad libitum consumption was advised for all subjects.	Weeks eight to 16 were a supervised weight maintenance phase.  Weeks 16 to 24 were an unsupervised weight maintenance phase.	CHO, PRO, Fat:  • High-fat: 11%, 57%, 29%.  • High-PRO: 34%, 35%, 28%.  • High-CHO: 49%, 24%, 21%.	Between baseline and eight weeks, the high-fat group (96.0±10.8kg to 89.4±10.3kg), the high-PRO group (93.2±14.5 kg to 87.8±13.7kg) and the high-CHO group (98.0±15.1kg to 93.7±14.5kg) all lost weight, with the high-fat and high-PRO groups losing more weight than the high-CHO group.	Between eight weeks and 24 weeks, the high-fat group (89.4±10.3kg to 88.9±10.6kg), the high-PRO group (87.8±13.7kg to 86.3±14.2kg), and the high-CHO group (93.7±14.5kg to 93.3±14.5 kg) all maintained their initial weight loss.	TG ↓ with all three diets, but the ↓ were significantly greater in the high-fat diet and high-PRO diet groups than the high-CHO group diet group.  Insulin levels ↓ in all three groups, with no differences between the groups.  LDL-C levels were significantly higher in the high-fat diet group than in the high-PRO diet group despite similar weight Δ (P=0.02).
Noakes M, Foster P et al, 2006  Study Design: Randomized Controlled Trial  Class: A  Rating:	N=67 subjects (55 women and 12 men). Age: 48 years. BMI: 33kg/m². N=24 on the very-low-CHO diet, N=22 on the very-low-fat diet and N=21 on the high-unsaturated-fat diet. Attrition rate: 19%.	Subjects were randomly assigned to one of three isocaloric diets for eight weeks of weight loss:  • Very-low-fat • High-unsaturated fat • Very-low-CHO.  Detailed dietary instruction and meal plans were provided to subjects every two weeks by an RD, and daily dietary checklists were used to assess compliance with the study protocol.	The eight weeks of weight loss was followed by four weeks of energy balance following the same diet plans prescribed for weight loss.	CHO, PRO, Fat:  • Very-low-CHO: 4%, 61%, 20%.  • Very-low-fat: 70%, 10%, 20%.  • High-unsaturated-fat: 70%, 10%, 20%.	There were NS differences in weight loss by diet composition; the very-low-CHO group lost 8.0±0.6kg, the very-low-fat group lost 6.7±0.7kg and the high-unsaturated-fat group lost 6.4±0.6kg. Percent fat loss also did not differ between the diets; the very-low-CHO group lost -4.5±0.5%, the very-low-fat group lost -4.0±0.5% and the high-unsaturated-fat group lost -4.0±0.6%.	Each diet groups lost weight over the eight-week energy restriction period and maintained this weight during the subsequent four-week period.	N/A (Study < 6 months)
Nordmann AJ et al 2006 Study Design: Meta-analysis Class: M Rating:	N=5 RCTs, with a total of 447 subjects.	A meta-analysis was done to compare the effects of low-CHO diets without energy restriction to energy-restricted, low-fat diets on weight loss, BP and lipid values in trials with dietary interventions with duration of at least six months.	Not applicable.	CHO, PRO, Fat:  • Low-CHO: <60g per day CHO.  • Low-fat: <30% fat.	After six months, individuals assigned to low-CHO diets had lost more weight than individuals randomized to low-fat diets (weighted mean difference, -3.3kg; 95% CI: -5.3, -1.4kg).	The difference in weight loss between diets at six months was no longer obvious after 12 months (weighted mean difference, -1.0 kg; 95% CI: -3.5, 1.5kg).	There were no differences in BP.  TG and HDL-C values Δ more favorably with low-CHO diets [after six months, for TG, weighted mean difference, -22.1mg per dL (-0.25mmol per L); 95% CI -38.1, -5.3mg per dL (-0.43 to -0.06mmol per L); and for HDL-C, weighted mean difference, 4.6mg per dL (0.12mmol per L); 95% CI: 1.5 to 8.1mg per dL (0.04 to 0.21mmol per L)], but TC and LDL-C values Δ more favorably with low-fat

							diets [weighted mean difference in LDL-C after six months, 5.4mg per dL (0.14mmol per L); 95% CI: 1.2 to 10.1mg per dL (0.03 to 0.26mmol per L)].
Phelan et al 2007 Study Design: Prospective Cohort Study Class: B  Rating:	N=891 subjects from the National Weight Control Registry (1998 to 2001) who reported 30-lb or more weight loss and one-year or more year weight loss maintenance.  N=96 (10.8%) who self-reported losing weight using a low-CHO diet  • 54.2% male • Mean age: 49 years.	Weight loss history and weight loss methods were self-reported at the time of entry into the study.  Weight was self-reported at study entry and subsequently at one-, two-, and three-year follow-ups.  Dietary intake was assessed by the Block FFQ.	Not applicable.	Not applicable.	Not applicable.	There were NS differences in weight regain between these individuals and other Registry members in the intent-to-treat analysis (7.0±7.1kg vs. 5.7±8.7kg).  Low-CHO diet participants were also more likely to have a shorter duration of successful weight maintenance (34.4±35.1 vs. 73.1±99 months; P=0.0001), compared with other Registry participants.	Not applicable.
Sacks FM, Bray GA et al, 2009 Study Design: Randomized clinical trial Class: A Rating:	N=645 subjects (397 women, 248 men).  Age: 52 years.  BMI: 33kg/m².  Attrition rate at two years: 20%.	Subjects were randomly assigned to one of four energy-reduced (-750kcal per day) diet groups: low-fat, average PRO; low-fat, high PRO; high-fat, average PRO; or high-fat, high-PRO. Subjects were offered group and individual counseling session for two years, and daily web-based food records were used to assess compliance with the study protocol. Weight measurements were taken at baseline, six months and two years.	Not applicable.	CHO, PRO, Fat:  • Low-fat, average PRO: 65%, 20%, 15% • Low-fat, high-PRO: 55%, 20%, 25% • High-fat, average PRO: 45%, 40%, 15% • High-fat, high-PRO: 35%, 40%, 25%.	At six months all groups lost a similar amount of weight (6kg or ~7% of initial weight), but began to regain weight after 12 months.	At two years, weight loss remained similar in those assigned to the 15% PRO and 25% PRO diets (-3.0 and -3.6kg, respectively); in those assigned to the 20% and 40% fat diets (-3.3kg for both groups); and in those assigned to the 65% and 65% aCHO diets (-2.9 and -3.4kg, respectively) (P>0.20 for all comparisons).	All diets reduced CVD and diabetes risk factors at six months and two years.  The low-fat diets and the highest CHO diet ↓ LDL-C levels more than the high-fat diets and the lowest CHO diet (P=0.0001).  The lowest CHO diet ↑ HDL-C level more than the high-st CHO diet (p=0.02).  All the diets ↓ TG levels and BP similarly, and all diets, except the highest CHO diet, ↓ fasting serum insulin levels (P=0.07).
Westerterp-Plantenga MS, Lejeune MP et al, 2004 Study Design: Randomized Controlled Trial Class: A Rating:	N=148. Mean age: 45 years. Mean BMI: 29kg/m <sup>2</sup> .	Not applicable.	Subjects were randomly assigned to a very low-energy diet (2.1mJ per day) for four weeks, with one group receiving a 48.2g per day PRO supplement to add to their regular diet.	CHO, PRO, Fat:  • Regular-PRO: 15% PRO.  • High-PRO: 18% PRO.	Not applicable.	After three months, percentage of weight regain (17% vs. 37 %) was significantly lower in the higher-PRO group compared to control (P<0.05).  BMI was also significantly lower in the higher-PRO group compared to control (27 vs.	Not applicable. (Study less than six months.)

			28kg/m <sup>2</sup> ; P<0.05).	
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# Research Design and Implementation Rating Summary

For a summary of the Research Design and Implementation Rating results, click here.

#### Worksheets

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